Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c) (179)(i)(D) and (190)(i)(B) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(179) * * *

(i) * * *

(D) Ventura County Air Pollution Control District.

(*1*) Rule 74.7, adopted on January 10, 1989.

* * * * *

(190) * * *

(i) * * *

(B) Bay Area Air Quality Management District.

(*1*) Rule 8–18, adopted on March 4, 1992.

* * * * *

[FR Doc. 95–3861 Filed 2–15–95; 8:45 am]

BILLING CODE 6560–50–W

40 CFR Part 52

[CA 102–6–6837a; FRL–5145–5]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Bay Area Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on a revision to the California State Implementation Plan. The revision concerns a rule from the Bay Area Air Quality Management District (BAAQMD). This approval action will incorporate this rule into the federally approved SIP. The intended effect of approving this rule is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The revised rule controls VOC emissions from valves and flanges at chemical plants. Thus, EPA is finalizing the approval of this revision into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

DATES: This final rule is effective on April 17, 1995, unless adverse or critical comments are received by March 20, 1995. If the effective date is delayed, a timely notice will be published in the **Federal Register**.

ADDRESSES: Copies of the rule and EPA's evaluation report for the rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule are available for inspection at the following locations:

Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, S.W., Washington, D.C. 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 92123–1095.

Bay Area Air Quality Management District, 939 Ellis Street, San Francisco, CA 94109.

FOR FURTHER INFORMATION CONTACT: Duane F. James, Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901, Telephone: (415) 744–1191.

SUPPLEMENTARY INFORMATION:

Applicability

The rule being approved into the California SIP is BAAQMD's Rule 8–22, ''Valves and Flanges at Chemical Plants.'' This rule was submitted by the California Air Resources Board (ARB) to EPA on September 28, 1994.

Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included the San Francisco-Bay Area (Bay Area). 43 FR 8964, 40 CFR 81.305. Because this area was unable to meet the statutory attainment date of December 31, 1982, California requested under section 172 (a)(2), and EPA approved, an extension of the attainment date to December 31, 1987. 40 CFR 52.222. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the 1977 Act, that the above district's portion of the California SIP was inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991, for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in pre-amendment guidance.[1] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. The Bay Area is classified as moderate;[2] therefore, this area was subject to the RACT fix-up requirement and the May 15, 1991 deadline.

The State of California submitted many revised RACT rules for incorporation into its SIP on September 28, 1994, including the rule being acted on in this notice. This notice addresses EPA's direct-final action for BAAQMD's Rule 8–22, ''Valves and Flanges at Chemical Plants.'' The BAAQMD adopted Rule 8–22 on June 1, 1994. This submitted rule was found to be complete on November 22, 1994, pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51 Appendix V[3] and is being finalized for approval into the SIP.

Rule 8–22 prohibits volatile organic compound (VOC) emissions in excess of 10,000 parts per million (ppm) from valves and flanges at chemical plants. VOCs contribute to the production of ground level ozone and smog. This rule was originally adopted as part of BAAQMD's effort to achieve the National Ambient Air Quality Standard (NAAQS) for ozone and in response to EPA's SIP-Call and the section 182(a)(2)(A) CAA requirement. The following is EPA's evaluation and final action for this rule.

---

[1] Among other things, the pre-amendment guidance consists of those portions of the proposed Post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 **Federal Register** Notice'' (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988); and the existing control technique guidelines (CTGs).

[2] The Bay Area retained its designation of nonattainment and was classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 55 FR 56694 (November 6, 1991).

[3] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

EPA Evaluation and Action

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in the various EPA policy guidance documents listed in footnote 1. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the pre-amended Act.

For the purpose of assisting state and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to ''fix-up'' their RACT rules. See section 182(a)(2)(A). The CTG applicable to this rule is entitled, ''Control of Volatile Organic Compound Leaks from Synthetic Organic Chemical and Polymer Manufacturing Equipment (EPA–450/3–83–006).'' Further interpretations of EPA policy are found in the Blue Book, referred to in footnote 1. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

The BAAQMD's submitted Rule 8–22, ''Valves and Flanges at Chemical Plants,'' includes the following significant changes from the current SIP:

1. The exemption for valves and flanges on instrument and sample lines with diameters of 1.8 cm (0.75 in.) or less has been deleted.

2. Research and development facilities must now satisfy certain criteria in order to be exempt from the rule.

3. The rule transfers the regulation of chemical plants with 100 or more valves to the BAAQMD's Rule 8–18, ''Valves and Connectors at Petroleum Refineries, Chemical Plants, Bulk Plants and Bulk Terminals,'' which has a leak standard of 1,000 ppm. EPA proposed an approval of Rule 8–18 on December 17, 1993 (58 FR 65959).

4. EPA Method 21 is the test method used to determine leaks.

5. Quarterly inspections are now required for accessible valves while annual inspections continue for inaccessible valves.

6. The rule requires records of the identification codes, types, and locations of each valve.

7. The rule requires records of the dates of all inspections, re-inspections, and the measured leak concentrations of valves and flanges where the emission standard of the rule has been exceeded.

8. The rule requires monthly records of all non-repairable valves until the next unit turnaround when these valves must be repaired.

9. The rule requires that all records be maintained for at least 5 years.

EPA has evaluated the submitted rule and has determined that it is consistent with the CAA, EPA regulations, and EPA policy. Therefore, BAAQMD's Rule 8–22, ''Valves and Flanges at Chemical Plants,'' is being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and Part D.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

EPA is publishing this notice without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective April 17, 1995, unless, by March 20, 1995, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent notice that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective April 17, 1995.

Regulatory Process

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et. seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over population of less than 50,000.

SIP approvals under sections 110 and 301(a) and subchapter I, Part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S. Ct. 1976); 42 U.S.C. 7410 (a)(2).

The OMB has exempted this action from review under Executive Order 12866.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1982.

Dated: January 17, 1995.

Felicia Marcus,

Regional Administrator.

Subpart 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart F—California

2. Section 52.220 is amended by adding paragraph (c)(199)(i)(A)(4) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(199) * * *

(i) * * *

(A) * * *

(4) Rule 8–22, adopted on June 1, 1994.

* * * * *

[FR Doc. 95–3864 Filed 2–15–95; 8:45 am]

BILLING CODE 6560–50–W

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 410

[BPD–424–F]

RIN 0938–AE94

Medicare Program; Medicare Coverage of Prescription Drugs Used in Immunosuppressive Therapy

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations to provide Medicare coverage for prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which Medicare payment is made. This rule reflects the enactment of section 1861(s)(2)(J) of the Social Security Act that provides Medicare coverage for prescription drugs used in immunosuppressive therapy for a period of up to 1 year from the date of discharge from an inpatient hospital stay during which the Medicare-covered organ or tissue transplant was performed.

This final rule also implements section 13565 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66) and section 160 of the Social Security Act Amendments of 1994 (Public Law 103–432) that, beginning January 1, 1995, expand Medicare coverage for prescription drugs used in immunosuppressive therapy from 1 year to a phased-in period of 3 years from the date of discharge from a hospital stay during which the Medicare-covered organ or tissue transplant was performed.

DATES: These regulations are effective January 1, 1995, the effective date of the statute.

FOR FURTHER INFORMATION CONTACT: Debra McKeldin, (410) 966–9671.

SUPPLEMENTARY INFORMATION:

I. Background

Before enactment of section 9335(c) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Public Law 99–509, there was no specific Medicare benefit that provided for Medicare Part B coverage of prescription drugs used in immunosuppressive therapy.

OBRA '86 added subparagraph (J) to section 1861(s)(2) of the Social Security Act (the Act) to provide Medicare coverage for immunosuppressive drugs, furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period not to exceed 1 year after the transplant procedure. Coverage of these drugs under Medicare Part B began January 1, 1987.

We published a proposed rule with a 60-day public comment period (53 FR 1383) on January 19, 1988, which we discuss below. Before its publication, however, the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100–203, was enacted and effective December 22, 1987, revised section 1861(s)(2)(J) of the Act so that the scope of coverage was expanded from coverage of ''immunosuppressive drugs'' to coverage of ''prescription drugs used in immunosuppressive therapy.'' We issued the proposed rule before changes could be made to reflect this new terminology. We did propose, however, coverage that would include, in addition to immunosuppressive drugs, other drugs used in conjunction with immunosuppressive therapy. In addition, in April 1988, we issued manual instructions to Medicare contractors that reflected the new terminology.

Also, section 202 of the Medicare Catastrophic Coverage Act of 1988, Public Law 100–360, enacted on July 1, 1988, extended coverage of drugs used in immunosuppressive therapy to include drugs furnished in subsequent years after the first year following a covered transplant. It also extended coverage to include drugs used following a noncovered transplant irrespective of any prescribed time limitations. This extended coverage, which was to be effective on January 1, 1990, was part of the outpatient drug coverage set forth in section 202(a) of Public Law 100–360. On December 19, 1989, however, these provisions of the law were repealed as part of the Medicare Catastrophic Coverage Repeal Act of 1989, Public Law 101–234. As a result, the extended Medicare coverage of drugs used in immunosuppressive therapy set forth in Public Law 100–360 never became effective.

Since publication of the proposed rule, section 13565 of the Omnibus Reconciliation Act of 1993 (OBRA '93), Public Law 103–66, amended section 1861(s)(2)(J) of the Act. In accordance with OBRA '93, the coverage period for prescription drugs used in immunosuppressive therapy will be extended to 18 months from the hospital discharge date following a covered transplant procedure for drugs furnished in 1995; 24 months for drugs furnished in 1996; 30 months for drugs furnished in 1997; and 36 months for drugs furnished after 1997. Subsequently, section 160 of the Social Security Act Amendments of 1994, Public Law 103–432, enacted on October 31, 1994, allows us to administer the OBRA '93 provision in such a way that coverage would be continued consecutively.

Since this provision is self-executing, we have issued it as part of this final rule, rather than in proposed form.

II. Provisions of the Proposed Rule

In the January 1988 proposed rule, we proposed to amend 42 CFR part 410 (''Supplementary Medical Insurance (SMI) Benefits'') to incorporate the following:

- Cover immunosuppressive drugs under Medicare Part B by revising § 410.10 to include immunosuppressive drugs in the term ''medical and other health services'';
- Add a new § 410.31 to provide specifically for coverage of immunosuppressive drugs generally; and
- Add a new § 410.65 to provide Medicare coverage of drugs used in immunosuppressive therapy, that are furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period of up to 1 year beginning with the date of discharge from the inpatient hospital stay during which the transplant was performed (the proposed rule did not, of course, include the OBRA '93 phased-in extension to the coverage period that follows a Medicare approved transplant). We proposed that coverage include: (1) Those immunosuppressive drugs specifically labeled as immunosuppressive drugs and approved for marketing by the Food and Drug Administration (FDA) and (2) other drugs that FDA-approved labeling indicates are used in conjunction with immunosuppressive drug therapy.

III. Discussion of Comments

We received 11 timely comments in response to the January 1988 proposed rule. The comments were from representatives of hospitals, medical centers, national associations representing health care professionals, and a university. The specific comments and our responses follow:

Comment: Several commenters suggested that coverage of immunosuppressive drugs be extended beyond 1 year.

Response: As stated earlier, since the publication of the proposed rule, OBRA